(e) A licensee shall retain a record of each check and test required by this section for three years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1) of this section, the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2) of this section, the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test.

(3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test.

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61783, Dec. 2, 1994]

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;

(2) Calibrate two separated readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(d) A licensee shall retain a record of each survey instrument calibration for three years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

(a) This section does not apply to unit dosages of alpha- or beta- emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements.

(b) For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as

appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

[59 FR 61783, Dec. 2, 1994]

§ 35.53 Measurement of dosages of unsealed byproduct material for medical use.

A licensee shall:

(a) Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use.

(b) Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements;

(c) Retain a record of the measurements required by this section for three years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's or human research subject's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries);

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61784, Dec. 2, 1994]

§ 35.57 Authorization for calibration and reference sources.

Any person authorized by §35.11 of this part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to §32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each;

(b) Any byproduct material listed in §§35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct material listed in §§35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

§ 35.59 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.

(c) To satisfy the leak test requirements of this section, the licensee must:

(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(2) Take teletherapy and other device source test samples when the source is in the ''off'' position; and

(3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.

(d) A licensee shall retain leakage test records for five years. The records